

TABLE 146-continued

Female Sexual Function Index Total and Domain Scores:									
Category	Score	4 μ g		10 μ g		25 μ g		Placebo	
		Mean	SD	Mean	SD	Mean	SD	Mean	SD
Lubrication	Baseline	2.1	1.25	2.3	1.25	2	1.19	2	1.29
	Week 12	3.9	1.84	4.4	1.56	4.3	1.65	3.6	1.77
	Change	1.84	1.782	2.12	1.612	2.36	1.744	1.64	1.871
	LS Mean	1.835	0.4023	2.243	0.0012	2.3	0.0003	1.591	—
Orgasm	Baseline	2.7	1.74	2.9	1.74	2.4	1.68	2.4	1.73
	Week 12	3.8	1.89	4.1	1.75	4.1	1.66	3.7	1.97
	Change	1.12	1.93	1.09	1.821	1.68	1.857	1.31	1.86
	LS Mean	1.162	0.9978	1.273	0.9424	1.59	0.0763	1.189	—
Satisfaction	Baseline	2.9	1.37	3.2	1.43	2.9	1.37	2.9	1.49
	Week 12	4.2	1.54	4.4	1.37	4.6	1.35	4.1	1.55
	Change	1.31	1.512	1.24	1.534	1.64	1.613	1.23	1.661
	LS Mean	1.256	0.8798	1.382	0.3484	1.628	0.0063	1.165	—

While the pharmaceutical compositions and methods have been described in terms of what are presently considered to be practical and preferred embodiments, it is to be understood that the disclosure need not be limited to the disclosed embodiments. It is intended to cover various modifications and similar arrangements included within the spirit and scope of the claims, the scope of which should be accorded the broadest interpretation so as to encompass all such modifications and similar embodiments. This disclosure includes any and all embodiments of the following claims.

What is claimed is:

1. A method for treating moderate to severe dyspareunia in a subject, the method comprising: intravaginally administering to the subject a dosage form comprising a liquid pharmaceutical composition, wherein the viscosity of the composition ranges from about 50 cP to about 1000 cP at 25° C., wherein the dosage form is manually inserted into the vagina, wherein the composition comprises estrogen as the only active agent, wherein all of the estradiol is encapsulated in the capsule, wherein the composition comprises about 4 μ g to about 25 μ g of estradiol, wherein the administration comprises inserting the capsule once daily for two weeks and twice weekly thereafter, and wherein upon contact of the dosage form with the vaginal mucosa, the composition comprising the estrogen is released into the vaginal tissue.

2. The method of claim 1, wherein the dosage form is a capsule.

3. The method of claim 1, wherein the capsule is a soft gelatin capsule.

4. The method of claim 1, where the composition comprises about 4 μ g to about 25 μ g of estradiol.

5. The method of claim 1, wherein administration of the dosage form results in an increase in the percentage of vaginal superficial cells within about two to six weeks from the first administration.

6. The method of claim 1, wherein administration of the dosage form results in a decrease in the percentage of vaginal parabasal cells within about two to six weeks from the first administration.

7. The method of claim 1, wherein administration of the dosage form results in a decrease in vaginal pH within about two to six weeks from the first administration.

8. The method of claim 1, wherein administration of the dosage form results in a decrease in the severity of moderate to severe dyspareunia within about two to six weeks from the first administration.

9. The method of claim 4, wherein the composition contains 4 μ g estradiol or 10 μ g estradiol.

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